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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,063	06/22/2001	Corey E. Nislow	CYTOP003	6972

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EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,063	NISLOW ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6,9-12,14,15,17-27,29,30,32-41 and 43-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,32,33,37-41,43,44 and 47-53 is/are allowed.
- 6) ☒ Claim(s) 2-6,10-12,14,15,17-22,25-27,29,30,34-36,45,46 and 54 is/are rejected.
- 7) ☒ Claim(s) 23,24,55, & 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 8/2/04, have been fully considered and they are deemed to be persuasive to overcome previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Unfortunately, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Due to the newly applied rejections, summarized below, the finality of the previous office action, mailed 6/10/04, is hereby withdrawn.

LACK OF ENABLEMENT

Claims 4, 5, 19, 20, 34, 35, 45, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those

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in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

Instant claim 4 is worded as being directed to requiring the usage of modified cell strains which contain a deletion mutant for each non-essential gene in a parent strain. Said claim 4 is reasonably interpreted to require the presence of such a deletion mutant for all such non-essential genes. It is noted that "each" in claim 4 is utilized as a pronoun. The pronoun definition of "each" in the enclosed New Riverside University Dictionary indicates that "Every one of a group regarded individually" is meant thereby. Thus, instant claim 4 apparently requires a deletion mutant for every one of the non-essential genes in a parent strain. The determination of every one of such non-essential genes is unpredictable as being directed to a complex and yet undefined result for complex organisms including bacteria etc. utilized for parent strains in the practice of the instant invention. Ashby et al. substantiates the incompleteness of non-essential gene listing for *S. cerevisiae* in column 10, lines 33-58, wherein even the essential genes are yet not fully determined and finding essential genes requires identification practice as in column 10, lines 47-58, wherein there is no prediction of what must be performed to find all essential genes thus leaving other as non-essential. Instant claim 5 also contains this issue due to its dependence from claim 4, as well as correspondingly claims 19, 20, 34, 35, 45, and 46. In summary, it is reasonably undue

experimentation due to unpredictable experimentation required for the practice of instant claims 4, 5, 19, 20, 34, 35, 45, and 46 to practice a deletion mutant for "each" non-essential gene in a parent strain of which *Saccharomyces cerevisiae* is an example discussed in Ashby et al.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 3, 6, 10-12, 14, 15, and 54 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Ashby et al. (P/N 6,518,035).

Ashby et al. summarizes the invention in the title and abstract to be directed to drug screening using co-culture methods directed to inhibition of the expression or activity of a protein encoded by a target gene. In column 2, line 59, through column 3, line 10, first and second cell types of the same type and species is described which indicates the usage of congenic cell types as in the preamble of instant claim 6. In particular, *Saccharomyces cerevisiae* is a cell type employed therein with mutant essential genes utilized in such cells as described in column 5, line 64, through column 6, line 44, for drug screening as also instantly claimed. Mutant essential gene practice, as in the instant claims, is also further described in column 10, lines 24-67. The

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spatial/positional imaging (as also in instant claims 10 and 11) of cell strains for determination of drug effects is shown in Figure 3 wherein the data is summarized in Figures 1 and 2. In the specification in column 5, lines 8-45, these Figures are described including the usage of a FluorImager which is imaging practice to detection fluorescence phenotype as also required for instant claim 6. The signal from the imaging is analyzed via subtraction of fluorescence signal from a control plate plus subjected to other calculations as described in column 5, lines 27-34. Such calculations, even the subtraction as noted above, are reasonably one or more algorithms for quantitative use in said analysis as instantly required for the imaging practice of the instant claim 6. The drug treatment effects comparisons described in said Figure descriptions anticipates the comparing practice of instant claim 6, last 4 lines. The experimental details directed to *Saccharomyces cerevisiae* usage corresponding to the above discussed Figures is set forth in the reference in column 35, line 61, through column 39, line 61, including a variety of essential gene manipulation to improve the sensitivity of the method. Thus an embodiment of instant claim 6 is anticipated by the above disclosures. The deletion of non-essential genes is also disclosed in Ashby et al. in column 10, lines 59-65, wherein deletion of a redundant or duplicated gene (singular) as also required in instant claims 2 and 3. The target gene may be part of a cluster of genes in a pathway which is thus analyzed as in Ashby et al. as described in column 8, line 23, through column 9, line 13, and also the practice cited in instant claim 12. Various applications of the invention of Ashby et al. are summarized in column 31, line 25, through column 35, line 60, wherein various

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pharmaceutical applications are described starting in column 34, line 50, wherein lead compounds may be identified which such listing is reasonably a database as in instant claim 14, albeit not cited as a database per se. Also non-morphological analyses as in instant claim 15 are included via PCR product characterizations as in the sentence bridging columns 31 and 32.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 18, 21, 22, 25-27, 29, 30, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashby et al.(P/N 6,518,035); taken in view of Price et al.(P/N 5,548,661).

Ashby et al. has been summarized above regarding the description of phenotypic imaging of parent and modified cell strains for drug treatment analysis. Ashby et al, however, does not describe a computer program product or medium as cited in instant claim 21.

Price et al. summarizes both prior art as well as an invention directed to imaging of cell samples in the abstract as well as in column 1, line 30, through column 8, line 14. Algorithm analysis of images as also instantly claimed as well as described in basic form in Ashby et al. is described in Price et al. in column 6, line 31, through column 7, line 33. Fluorescence imaging as also utilized in Ashby et al. is also described in summary in Price et al. in column 9, lines 3-17. Price et al. motivates and suggests the imaging practice therein for improvement in segmentation etc. for such imaging in column 5, line 35, through column 6, line 29. The implementation of the methodology of Price et al. as a computer program product, medium, etc. is described via the computerization discussions in column 9, line 18, through column 12, line 27, with particular attention to the column 12, lines 14-27, section. The applications of the Price et al. invention include cytometry of attached cells with a variety of materials being imagable as summarized in column 19, lines 18-51. It is noted that the Ashby et al. cells are attached in assay plates for imaging purposes.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the Ashby et al. cell strain/drug screening as summarized above with imaging which is motivated in Price et al. to be an improvement thereon as discussed above including computerization for automatic ease of operation thus resulting in the practice of the above listed instant claims.

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CLAIM OBJECTIONS

Claims 23, 24, 55 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9, 32, 33, 37-41, 43, 44, and 47-53 are allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 7, 2004

Ardin H. Marschel 12/7/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER